§ 1301.01

1301.33 Application for bulk manufacture of Schedule I and II substances.

1301.34 Application for importation of Schedule I and II substances.

1301.35 Certificate of registration; denial of registration.

1301.36 Suspension or revocation of registration; suspension of registration pending final order; extension of registration pending final order.

1301.37 Order to show cause.

HEARINGS

1301.41 Hearings generally.

1301.42 Purpose of hearing.

1301.43 Request for hearing or appearance; waiver.

1301.44 Burden of proof.

1301.45 Time and place of hearing.

1301.46 Final order.

MODIFICATION, TRANSFER, AND TERMINATION OF REGISTRATION

1301.51 Modification in registration.

1301.52 Termination of registration; transfer of registration; distribution upon discontinuance of business.

SECURITY REQUIREMENTS

1301.71 Security requirements generally.

1301.72 Physical security controls for nonpractitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas.

1301.73 Physical security controls for nonpractitioners; compounders for narcotic treatment programs; manufacturing and compounding areas.

1301.74 Other security controls for nonpractitioners; narcotic treatment programs and compounders for narcotic treatment programs.

1301.75 Physical security controls for practitioners.

1301.76 Other security controls for practitioners.

1301.77 Security controls for freight forwarding facilities.

EMPLOYEE SCREENING—NON-PRACTITIONERS

1301.90 Employee screening procedures.

1301.91 Employee responsibility to report drug diversion.

1301.92 Illicit activities by employees.

1301.93 Sources of information for employee checks

AUTHORITY: 21 U.S.C. 821, 822, 823, 824, 831, 871(b), 875, 877, 886a, 951, 952, 953, 956, 957, 958, 965.

SOURCE: 36 FR 7778, Apr. 24, 1971, unless otherwise noted. Redesignated at 38 FR 26609, Sept. 24, 1973.

GENERAL INFORMATION

§ 1301.01 Scope of this part 1301.

Procedures governing the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances pursuant to sections 301–304 and 1007–1008 of the Act (21 U.S.C. 821–824 and 957–958) are set forth generally by those sections and specifically by the sections of this part.

[62 FR 13945, Mar. 24, 1997]

§ 1301.02 Definitions.

Any term used in this part shall have the definition set forth in section 102 of the Act (21 U.S.C. 802) or part 1300 of this chapter.

[62 FR 13945, Mar. 24, 1997]

§ 1301.03 Information; special instructions.

Information regarding procedures under these rules and instructions supplementing these rules will be furnished upon request by writing to the Registration Section, Drug Enforcement Administration. See the Table of DEA Mailing Addresses in §1321.01 of this chapter for the current mailing address.

[75 FR 10676, Mar. 9, 2010]

REGISTRATION

§ 1301.11 Persons required to register; requirement of modification of registration authorizing activity as an online pharmacy.

(a) Every person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§ 1301.22 through 1301.26. Except as provided in paragraph (b) of this section, only persons actually engaged in such activities are required to obtain a registration; related or affiliated persons who are not engaged in such activities are not required to be registered. (For example, a stockholder or parent corporation of a corporation manufacturing controlled substances is not required to obtain a registration.)